2012 were analyzed for their ASMR ratings. Analysis were conducted to identify new trends and compare them for products based on their indications, comparators and launch timing. **RESULTS:** Analysis of 2011-2012 assessments by TC shows that majority of products (73%) received an ASMR rating of IV (minor improvement). Approximately 27% of the products received an ASMR rating of III and V. A new trend in TC's assessment is the assignment of two ASMR ratings for one product for different subgroups or patient line of treatment. During last one year 3 out of 11 products received two ASMR ratings. None of the products received ASMR ratings of I and II. The products that received ASMR rating of V (no improvement) were indicated for cardiovascular, epilepsy and bone metastases. All assessments included analysis of intervention's data versus one or more comparators. **CONCLUSIONS:** France TC's assessments trends show need for robust comparative effectiveness data to obtain better ASMR ratings, which affects both pricing and market access of new products. Future products would need subgroup analysis to obtain high ASMR ratings for all patient populations.

PHP35

SYSTEMATIC REVIEW OF KEY ISSUES IN ENDOSCOPE REPROCESSING – GUIDELINE ADHERENCE, HEALTH OUTCOMES AND RESOURCE USE

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OBJECTIVES: Safe endoscope reprocessing requires meticulous adherence to guidelines. Human error is a principal cause of deficient reprocessing. Approaches vary from fully manual processes, to semi-automatic reprocessors, or fully automated cleaner and reprocessors. We assessed key issues in endoscope reprocessing related to guideline adherence, health and resource outcomes and staff burden. **METHODS:** PubMed was searched from January 1, 2007 to March 7, 2012. Search terms: ((Endoscope OR endoscopy) AND (Reprocessing OR Cleaning OR Disinfection OR Biofilms)). Abstracts were screened by 2 independent reviewers and included according to research areas: 1) adherence to endoscope reprocessing guidelines; 2) endoscopy related adverse contamination outcomes and; and 3) adverse effects of endoscope reprocessing on staff. Reference lists of key papers were searched. **RESULTS:** Six studies assessed guideline adherence. Non-adherence levels varied considerably with a trend for less developed health care systems to have poorer adherence. For study question 2, 19 articles reported 7 infection outbreaks, 6 pseudo-outbreaks and 4 toxic reactions related to endoscope procedures. The majority of events could have been prevented if standard reprocessing practices were followed. Eight studies (1 each from Canada, Japan and US and 5 from Europe) considered the impact of device reprocessing on staff health, time, or the associated costs. Two studies reported that manual reprocessing had a significant health impact on staff including respiratory ailments and physical discomfort. One study reported that in a single hospital reprocessing time was 6.2 hours longer per day with manual vs. automated procedures; this had a resultant impact on costs. **CONCLUSIONS:** Effective reprocessing is vital to ensure safe use of endoscopes. Guideline adherence is variable, and poor standards can lead to adverse outcomes. Manual reprocessing is associated with considerable health burdens for staff. Automated reprocessing could improve guideline adherence and reduce the burden on staff, as well as reduce costs. Further studies in this area are warranted.

PHP36

ANALYSIS OF THE REIMBURSEMENT DECISIONS OF THE NATIONAL HEALTH INSURANCE FUND OF HUNGARY (2007-2011)

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OBJECTIVES: Our goal was to analyze the Hungarian drug reimbursement decisions - through the reimbursement of new molecular entities (NME) in the period of 2007-2011. **METHODS:** NME's were collected from the official drug reimbursement list published monthly on the website of the National Health Insurance Fund of Hungary (NHIF). Drugs with hospital reimbursement were excluded from the analysis, as their reimbursement process differs. There are two ways to reimburse an Rx NME in Hungary: Route A: NHIF is the final decision maker, there is no need for legislation change. Route B: In case of e.g. new restricted indication or a new ATC4 level of a given NME, the final decison makers are, Ministry of Health & previously Ministry of Finance, currently Ministry of Economy. In these latest cases a ministerial decree is published, containing the reimbursement list of NME's. **RESULTS:** Within the observed period 86 new molecules gained reimbursement from the Drug Budget. The most NME's gained reimbursement in 2008 (23 NME's). A total of 33% of the products belong to two ATC categories: A and L, and most of NME's (40%) are fully reimbursed. 34 % of the products needed Route B to gain reimbursement. More than half of these products (16 molecules) gained reimbursement in 2008, however no such decision was made in 2009 and only 3 molecules have been reimbursed in 2010 and 2011, respectively! **CONCLUSIONS:** The number of reimbursement decisions made through Route A didn't change in this 5-year period. However the number of Route B reimbursement decision dropped significantly from 2008, resulting a significant market access delays for the Hungarian patients.

PHP37

NEW CLASSIFICATION OF TRADITIONAL AND INNOVATIVE PHARMACEUTICAL PAYMENT METHODS

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OBJECTIVES: To suggest a new classification of different pharmaceutical payment methods and to analyze the implementation of those methods in different health care settings of IQ Partners' Countries. This division will facilitate the comparative analysis of the impact of different payment methods on health care costs, efficiency, quality and equity. **METHODS:** Data on pharmaceutical payment methods were obtained through a review of the available literature. The search included relevant economic and medical databases, journals and books, conference materials and other projects. Different examples of payment methods were extracted from publications (95 positions) and classified. The implementation of those methods in different countries was also described. **RESULTS:** The practical classification of pharmaceutical payment methods was based on two main categories: traditional (well established and widely used) and innovative (implemented in recent years, depending on the country). A sub-classification was also outlined, related to the regulatory mechanisms of the methods in question: market driven, administrative regulations and market mechanisms with administrative settings (mixed). The traditional payment methods and schemes include: "free" prices, fixed prices, flexible prices, fixed budget, reference pricing, margins, rebate agreements, bonus agreements and patient's co-payment. The innovative payment methods include price volume agreements, cross-product agreements, risk-sharing, value-based pricing, framework agreements, cost-plus pricing, patient access schemes, portfolio deals, one price per patient, disease management. The second group was subsequently introduced in selected countries, including UK and US with a trend to be used in others countries (e.g. Poland). **CONCLUSIONS:** Innovative payment methods allow risk-sharing both related to costs and outcomes creating an additional platform for a dialogue between authorities and producers.

PHP38

POINT-OF-CARE DIAGNOSTIC TEST REIMBURSEMENT AND MARKET ACCESS: LESSONS FROM A SURVEY OF GLOBAL HEALTH TECHNOLOGY ASSESSMENTS

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OBJECTIVES: Point-of-care (POC) testing, also called near-patient, bedside, alternate-site or decentralized testing, includes all in vitro testing where conduct and analysis occurs outside the laboratory setting (e.g., physician office, at home), and within a short time period while the patient waits. Development of POC diagnostic tests (POCTs) has been on the rise in recent years and promises to reduce health care costs by reducing utilization of costly centralized laboratory-based testing, the need for follow-up office visits by patients to review laboratory test results, and/or sample shipment and storage. Despite the potential of POC testing, health systems and payers have been slow to adopt and reimburse such tests. To examine key issues influencing POCT reimbursement and market access, global health technology assessments (HTAs) were evaluated to identify stakeholder concerns contributing to the slow penetration of POCTs. **METHODS:** Published global POCT HTA recommendations were identified and reviewed to provide insights into criteria scrutinized and concerns registered by HTA agencies. **RESULTS:** POCT HTAs identified included those for cardiovascular, endocrine, oncologic, pulmonary/allergic, and infectious diseases, and those informing therapeutic or illicit drugs. In assessing POCTs, agencies scrutinized criteria generally fitting into four categories of evidence including Testing Logistics, Clinical Validity/Utility, Economic Value/Cost, and Ethical Concerns. For Testing Logistics: agencies scrutinized test turnaround time, platform accessibility and current penetration, required sample size, specimen collection and transport, and result/quality tracking; Clinical Validity/Utility: test performance (e.g., sensitivity, specificity, false positives/negatives) and agreement with/efficacy relative to lab-based tests, and impact on provider decision-making/patient outcomes; Economic Value/Cost: cost-offsets, cost-effectiveness, and cost-minimization; Ethical Concerns: implications of erroneous results and privacy issues. **CONCLUSIONS:** POC testing approaches hold potential to reduce health care costs while maintaining or improving patient outcomes. Evidence required to support POCT HTA should be considered during development of new POCTs to increase the likelihood of achieving reimbursement and market access.

PHP39

EXPLANING DIFFERENCES IN EU5 MARKET PENETRATION LEVELS AND RATES OF BIOSIMILARS: THE CASE OF EPOETINE, GRANULOCYTE-COLONY STIMULATING FACTOR, AND GROWTH HORMONES

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OBJECTIVES: Biosimilars are off-patent biologicals that shall provide cost savings and greater accessibility to biopharmaceuticals. Within the next five years, several top-selling biologics like Herceptin, Enbrel, Humalog, are due to loose patent protection. This opens business opportunities, but little is known about the biosimilar market. The main biosimilar product classes are biosimilars of Epoetine (EPO), Granulocyte-Colony Stimulating Factor (G-CSF) and Growth Hormoes (GH). Market penetration levels for these biosimilars differ substantially across Germany, France, UK, Italy and Spain (EU5). Literature does not provide an stringent explanation for these differences.We attempt to fill this gap by explaining the diverse levels of biosimilar uptake. **METHODS:** We model the diffusion process of biosimilars in pharmaceutical markets with a Bass diffusion model. Model parameters are estimated from IMS Health sales data on three Biosimilar classes in the EU5 countries. The estimated model parameters differ across countries and products. To explain these differences, we conduct several expert interviews.The theoretical lense guiding the interviews is Rogers theory of innovations and how properties of an innovation influence diffusion. **RESULTS:** We find that Germany and France account for approximately half the biosimilars market by value and a 34% and 17%

market share across Europe. G-CSFs have achieved the highest market penetration levels by value and GH the lowest across Europe. We identify four main drivers of market penetration differences. Price has the highest impact along with the response rate to the therapy. The efficacy of biosimilars in clinical trials as well as the economic mind-set of prescribers (office-based vs. hospital-based) also drive biosimilar market uptake. **CONCLUSIONS:** The study concludes with policy implications to regulate the uptake of biosimilars given different market conditions.

PHP40

AMNOG: PRICING REFORMS IN ACTION

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OBJECTIVES: The recent AMNOG health care reforms in Germany provide a unique view of a changing pricing system in Europe. With other European markets such as the UK planning similar reforms, we aimed to review the impact of AMNOG on drug pricing in Germany and distil lessons for other markets facing similar reforms. **METHODS:** Secondary research was conducted to review IQWiG's benefit assessment activity since the AMNOG reforms. The outcomes of these benefit assessments were assessed alongside rationale for decisions and pricing outcomes. **RESULTS:** At the time of writing, 24 products have been subject to benefit assessments by IQWiG. Of these, 12 were considered to show some level of added benefit relative to the comparator, with the remainder showing no benefit. Selection of inappropriate comparators was commonly cited by IQWiG as a reason that no additional benefit was demonstrated. Under AMNOG, products displaying no added benefit will be subject to automatic reference pricing, subjecting these products to generic pricing levels. As a result, there have been a number of high profile instances of manufacturers withdrawing products from the German market as a result of negative benefit assessment – most notably GSK with Trobalt and Pfizer with Xiapex. In instances where additional benefit is shown, Brilique is currently the only product has progressed through price negotiations with the GKV, resulting in a modest price premium. **CONCLUSIONS:** The AMNOG reforms provide an excellent live example of a national level shift towards a "value based" pricing system. The benefit assessments and consequent price levels may provide an indicator of pricing that may be achieved following the implementation of value based pricing in the UK. However, policy makers in the UK should be conscious of the potential negative implications of these reforms in the way of product withdrawals.

PHP41

USE OF SPECIAL PAYMENTS TO ENCOURAGE THE ADOPTION OF INNOVATIVE MEDICAL TECHNOLOGIES IN THE ENGLISH NHS

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OBJECTIVES: A number of jurisdictions have adopted special funding arrangements to provide extra payments to hospitals using certain technological innovations to encourage use where existing financing may be absent or insufficient. The objective of this research was to explore the use of these arrangements for medical technologies in the English NHS. **METHODS:** A structured on-line survey instrument was developed to gain insights into the use of special payments. An invitation to participate with a link to the on-line survey was disseminated to NHS hospital Finance Managers. A total of 25 surveys were returned and analysed. **RESULTS:** The majority (75%) of responding hospitals have sought support from Commissioners to approve special payments. In 35% of cases, the payment was for medical devices, followed by drugs (31%), diagnostics (19%), and other technologies (15%). Respondents highlighted specific technologies where special payments have been negotiated, including Transcatheter Heart Valves, Neuromodulation Implants, and Gastric Bands, among others. In most cases, such arrangements were requested because the technology was either excluded from the PbR system or the existing HRG tariff was not sufficient to cover costs. In half of the examples, the technology was fully or partially paid for. However, it was not uncommon for Commissioners to request additional evidence before making a decision or reject special payment applications altogether. A range of evidence (therapeutic benefit, reduced hospital admissions/length of stay, costs/cost-effectiveness) is considered to determine payment amounts. Once negotiated, payment arrangements are typically put in place for 1-3 years. Overall, NHS managers had mixed perceptions of the effectiveness of special payments and identified several challenges, such as a disinterest and insufficient expertise amongst Commissioners to consider submitted evidence and the length of time to agree payments. **CONCLUSIONS:** While special payments provide some flexibility for encouraging the adoption of technological innovation, a number of improvements are needed to effectively meet this aim.

PHP42

HEALTH ECONOMICS IN THE CZECH REPUBLIC AND INSURANCE COVERAGE DECISION MAKING IN 2008-2009: A RETROSPECTIVE ANALYSIS

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OBJECTIVES: Since 2008 the Czech legislation requires health economic analysis (HEA) to be a part of all new drug reimbursement applications submitted to State Institute for Drug Control (SUKL): without any specific guidelines, however. In order to see the real-world impact of the legislation change, we investigated past (2008/2009) innovative molecules' dossiers in terms of quality of their HEAs according to newly (2012) developed methodology of SUKL and also their impact on the respective decisions on coverage. **METHODS:** We selected all (22) applications for innovative drugs limited to specialized centers. We then briefly described the HEAs in terms of their perspective and type of analysis. The HEAs were further confronted with a 'HEA checklist' based on the new SUKL methodology to identify common drawbacks and faulty issues in past HEAs. Consequently the respective coverage decisions were investigated. **RESULTS:** Of the innovative molecules' 22 dossiers investigated, only in 13 (59%) HEA was present. Two (15%) were cost-minimization studies, the rest were cost-effectiveness analyses, of which three (23%) were cost-utility. There was no apparent standardization in the analyses along with an obvious lack of transparency. Indeed, 'proper description of input data and their sources' was the point in the HEA checklist to be most often marked as 'unsatisfactory'. Review of the consequent SUKL's coverage decisions revealed that, irrespective of the HEA quality and even presence, all 22 (100%) applications were given a positive coverage decision. **CONCLUSIONS:** The present pilot study showed that in the first two years since introducing the obligation of health economic analyses be part of coverage applications, the system was largely ineffective. This finding stresses the necessity of introduction of a standardized methodology into the assessment and appraisal processes. Moreover, our study identified the key problematic areas to be specifically addressed by both the authors and assessors of future analyses.

PHP43

HOW WILL HEALTH CARE REFORM IN RUSSIA AFFECT DRUG PRICING AND REIMBURSEMENT?

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OBJECTIVES: In an effort to remedy a highly fragmented system of health care financing, Russia has introduced a series of reforms targeted streamlining public and private funding. We aimed to understand how the recent reforms have impacted pricing and reimbursement and how this is expected to change in the future. **METHODS:** We conducted in-depth secondary research through an analysis of Russian health care policies including the new DLO reimbursement programme and the Essential and Most Important Medicines List (EML). Research was also conducted on the roles of private insurance companies and private out-of-pocket expenses. Expectation of how these reforms will shape pricing and reimbursement in the future was assessed through a qualitative survey of key payers. **RESULTS:** Increases in the percentage of GPD spent on health care and the procurement of additional funding have led to a boom in the size of the Russian pharmaceutical market. However, although medicines on the EML are fully reimbursed, coverage does not include drugs for most outpatients, resulting in significant out-of-pocket spending. Private insurers have also failed to produce competition due to lack of incentives and legislation has caused rises in drug pricing. Payers expect that economic growth and increased government spending on health care will continue to increase the commercial attractiveness of the Russian pharmaceutical market. However, several competing factors may cause legislative barriers to entry and create a more challenging pricing and reimbursement environment. These concerns arise from a newly imposed price cap on EML medicines, the exclusion of certain drugs from the EML, legislation encouraging domestic growth, and a lack of transparency regarding reimbursement decisions. **CONCLUSIONS:** New drug pricing regulations and funding will likely create advantages for domestic pharmaceutical companies while potentially decreasing foreign presence by creating a tougher pricing and reimbursement environment.

PHP44

PUBLIC FINANCING OF MEDICINES IN PORTUGAL (2007-2011): ACCESSIBILITY TO MEDICINAL PRODUCTS WITH NEW MOLECULES OR NEW THERAPEUTIC INDICATIONS

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OBJECTIVES: Accessibility (time to financing decision) to new medicines is a major concern in Europe. Recently the European Commission has proposed to streamline and reduce the duration of national decisions on pricing and reimbursement of new medicines. The objective of this study was to evaluate the accessibility to medicinal products with new molecules or new therapeutic indications (NMNTI) in Portugal, since 2007 and characterize the determinants of the assessment process by the Portuguese Ministry of Health. **METHODS:** Data on 119 NMNTI reimbursement applications to the PMH between January 2007 and June 2011 was kindly provided by submitting pharmaceutical companies. Time to financing decision was assessed using the Turnbull non-parametric estimator and variability in time to financing decision was explored using accelerated failure time regression models with Gaussian mixture distributions, both allowing for interval, left and right censoring. The likelihood of public financing and its determinants was evaluated through the estimation of logistic regression models. **RESULTS:** Median time from submission to decision 331 days (95%CI: 292-398) was excessive relative to those in the Law for the decision: 70 days (hospital) and 110 days (ambulatory). In hospital medicines no decision was taken in less than 70 days. Only 10% of the decisions from ambulatory drugs were taken within the timelines in the law. Of particular concern was median decision times for orphan medicines (718 days), oncology drugs (743 days) and new therapeutic indications of medicines already reimbursed (890 days). From a vast number of variables studied, only in cardiovascular medicines the likelihood of non-public financing was significant lower ($p=0.026$). **CONCLUSIONS:** Accessibility to new medicines or medicines with new therapeutic indications in Portugal is compromised by an excessively long assessment process by the Portuguese Ministry of Health. Of particular concern is accessibility to orphan and oncology drugs.